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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/089,846

06/06/2002

John Carter

3920-0110P

5250

7590

08/11/2008

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/089,846	Applicant(s) CARTER, JOHN	
	Examiner FRANK I. CHOI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/25/2008, 3/4/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-102, 104-106, 108, 124, 125, 127-130, 132-135, 137-147 and 149-164 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-96, 98, 99, 101, 102, 104-106, 108, 124, 125, 127-130, 132-135, 139-147, 149 and 152-164 is/are rejected.
- 7) ☒ Claim(s) 97, 100, 137, 138, 150 and 151 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 97,100,137,138,150,151 are objected to as being dependent on a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 89-96,98,99,101,102, 104-106, 108,124,125,127-130, 132-135,139-147, 149,152-164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Pat. 5,654,011) in view of Riley et al. (US Pat. 5,948,443), Klampfer et al., EP 0511895, Wawretschek et al. (US Pat. 4,061,741), DE 2457424, Herschler (US Pat. 4,514,421), Herschler (US Pat. 4,616,039), Memnon et al. and Maramag et al..

Jackson et al. disclose compositions and methods for providing dietary supplements to meet the needs of pre-perimenopausal women, including pregnant women, and to reduce the risk of cancer comprising copper, manganese, zinc, iron and vitamin C (Column 2, lines 25-51, Column 4, lines 13-23, Column 8, lines 30-68).

Riley et al. discloses a composition and method of reducing the risk of cancer by providing dietary supplements to women which comprise aspirin or bioequivalent forms, such as salicylic acid or other salicylates, iron, zinc, manganese, copper and Vitamin C (Column 9, lines 30-55, Column 21, lines 7-63, Table III).

EP 0511895 discloses a composition containing ascorbic acid, copper gluconate and manganese gluconate which has anti-cancer activity (Abstract, Page 4)

Klampfer et al. disclose that nonsteroidal anti-inflammatory agents are known for their chemopreventive activity and that sodium salicylate and aspirin induce apoptosis or leukemia cells (See pages 2386, 2393).

Wawretschek et al. disclose that the analgesic efficiency of sodium salicylate can be reinforced by combining with a salt of orotic acid (Claims 10, 30,39).

DE 2457424 disclose that zinc orotate is effective against cancer, with zinc being the active component and the orotate anion increasing bioavailability of the zinc (pages 1-3).

Hershler (US Pat. 4,514,421) disclose that administration of methylsulfonylmethane (MSM) and ascorbic acid and that administration of MSM resulted in reduction of tumor mass (Column 12, lines 7-47).

Hershler (US Pat. 4,616,039) disclose that methylsulfonylmethane is an assimilable source of sulfur (Abstract).

Memnon et al. disclose that vitamin C inhibits tumor growth (Abstract).

Maramag et al. disclose that vitamin C been suggested to be a protective agent against cancer development and a therapeutic agent against established cancer (Page 188). It is disclosed that vitamin C inhibited proliferation and survival of cancer cells and that preliminary results in an in vivo study showed that PC3 tumors responded to vitamin C treatment (page 194).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of copper orotate, manganese orotate, iron orotate, sodium salicylate, a source of assimilable sulfur and vitamin C. However, the prior art amply suggests

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the same as the prior art discloses dietary supplements which combine various nutrients, such as copper, manganese, vitamin C with salicylates for use in women and reducing the risk of cancer, the combination of sodium salicylate and salts of orotate to increase the efficacy of the sodium salicylate, the use of copper, manganese, iron and vitamin C for use in pregnant women and reducing the risk of cancer, MSM for treatment of cancer. Further, the prior art disclose and/or suggest that zinc orotate, ascorbic acid and sodium salicylate (NSAIDS) are effective neoplastic diseases. Finally, a composition containing ascorbic acid, manganese gluconate and copper gluconate is disclosed to be effective against cancer and that vitamin C has both protective and treatment activity against cancer. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art by providing the copper, iron, zinc and manganese as salts of orotate so as to increase the efficacy of the sodium salicylate and to combine copper, iron, zinc and manganese with sodium salicylate and vitamin C with the expectation that the composition would be suitable for use in pregnant women and for treatment of cancer, to further add MSM as it is effective in treating cancer.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The Applicant discusses case law relative to motivation, however, motivation is no longer a require element of a prima facie case of obviousness. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the field of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

There is no requirement that Jackson disclose treatment of cancer. However, protection against cancer does suggest usefulness in treatment of existing cancer. For example, ascorbic acid is disclosed to have protective activity against cancer and also therapeutic activity against cancer. The same reasoning applies to Riley. There is no requirement that Jackson or Riley disclose the use of salicylic acid or any alkali or alkaline metal earth metal salt thereof.

The Applicant argues that since combinations are not expressly disclosed that there is no reason to combine the compounds. However, as indicated above, the prior art does disclose combinations of compounds which are effective against cancer. Further, even if the prior art did not expressly disclose combinations of compounds effective against cancer. It would be obvious to combine compounds which are effective against cancer with the expectation that the combination would be effective against cancer. There is no requirement that the references must expressly disclose or suggest such a combination. The mere fact that there hundreds or thousands of possible combinations does not make the combination nonobvious. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). Clearly, there are hundreds and thousand of possible combinations of detergents or herbicides, nonetheless, the combinations above were found to be obvious.

The speculation that additional compounds could add adverse effects is insufficient to overcome the rejection. See e.g. *In re Jansen*, 187 USPQ 743, 745, 746 (C.C.P.A. 1975) (whether members of the medical profession would agree or disagree as to the safety of the drug

combination cannot control the determination of obviousness of the claimed drug combination and method of treatment using the same). Obviousness does not require absolute predictability. The Applicant's arguments would create a standard of obviousness where the combination itself would have to be tested to show that the combination is both safe and effective. Such a standard would equate to anticipation and is not required for a finding of obviousness.

The Applicant has submitted two Section 132 declarations as evidence of unexpected activity. However, these declarations and that the data in the Specification only show that sodium salicylate, ascorbic acid, copper gluconate and/or orotate and manganese gluconate and/or orotate are effective as anti-tumor agents. The claims are broader in scope in that they do not require the source of minerals be in the form of orotate or gluconate salts. See *In re Greenfield*, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972). In any case, the prior art does disclose a composition containing copper gluconate, manganese gluconate and ascorbic acid which is effective against cancer. Since sodium salicylate is also suggested to be effective against cancer, one of ordinary skill in the art would have reason to add sodium salicylate to the same with the expectation that the combination would be effective against cancer.

As such, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
August 12, 2008

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616